

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MU

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/412,539 10/04/99 KUCERA L 0044317U3

009629
MORGAN, LEWIS & BOCKIUS
1800 M STREET NW
WASHINGTON DC 20036-5869

HM12/0523

EXAMINER

COLEMAN, B

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

05/23/01

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/412,539

Applicant(s)
KUCERA et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 24, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-71, 95, 96, and 101 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-71, 95, 96, and 101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 20) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 56-71, 95, 96 and 101 are pending in the application.

This action is in response to applicants' amendment filed August 24, 2000. Claims 56, 58-60, 62-65, 95 and 101 have been amended.

Response to Amendment

Applicants' arguments filed August 24, 2000 have been fully considered with the following effect:

1. The receipt of a properly executed Request For Corrected Filing Date, the missing journal articles and a supplemental declaration are acknowledged.
2. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled a)-c) and e). However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled d) and f) of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.
 - d) The applicants' stated that "the ordinarily skilled artisan would understand that where a substituent is not indicated on an atom which is a member of a ring and which has the capacity for an additional covalent bond, a hydrogen atom would normally be present on that atom". However, one of the preferred embodiments for the pyrimidinyl moiety of formula VII is cytosine, where the bond between

Art Unit: 1624

position three and four is a double bond. It is not seen how a hydrogen atom at the three position would embrace this specific moiety.

Claims 56-71, 95, 96 and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

- f) The applicants' state that "there is sufficient antecedent basis for the limitation, since claim 56, the claim from which claim 68 depends, recites that "B" can be either a purinyl moiety or a pyrimidinyl moiety having Formula VI or Formula VII, respectively, with various substituents as recited in the claim". It is noted that guanine is a tautomer of the purinyl moiety where the 6 position is substituted by -OH and the 2 position is substituted by -NH₂, xanthine is a tautomer of the purinyl moiety where the 6 position is substituted by -OH and the 2 position is substituted by -OH, and hypoxanthine is a tautomer of the purinyl moiety where the 6 position is substituted by -OH. However, cytosine is a pyrimidinyl moiety where the 4 position is substituted by a -NH₂ moiety and **the bond between the 3 and 4 position is a double bond**, which is not embraced by the pyrimidinyl moiety of formulas VII in claim 56.

Art Unit: 1624

Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

3. The applicant's amendments are sufficient to overcome the claim objections labeled a)-f) of the last office action which are hereby withdrawn.

In view of the amendment dated August 24, 2000, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 101 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds *In re Buting* 163 USPQ 689. The remarkable advances

Art Unit: 1624

in chemotherapy have seen the development of specific compounds to treat specific types of cancer. The great diversity of diseases falling within the "tumor" category means that it is contrary to medical understanding that any agent could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

5. Claims 56-71 and 96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The search for anti-viral compounds has been slow indeed. The record is filled with new compounds that were highly touted only to show no benefit in human efficacy clinical trials. This reason for this is made clear by the first paragraph in the chapter titled "Antiviral Agents" in "Fields Virology, 3rd Ed." The approaches that have been fruitful take advantage of precisely defined molecular features of the virus and have resulted in effective therapy for herpes and AIDS. As is pointed out in the last paragraph of page 431 of "Fields Virology, 3rd Ed.": "The best targets for inhibition by antiviral are theoretically molecules serving a function unique to the virus". It is optimistic in the extreme to believe that given the history of anti-viral research that an agent will be effective on such a diverse class of viruses that share physical but not molecular features. The rejected claims call for the treatment of viruses generally. Despite intensive efforts, pharmaceutical science has been unable to find a way of getting a compound to be effective for


Art Unit: 1624

the treatment of viruses generally. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Monday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
May 21, 2001